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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,475	01/22/2002	Paul B. Fisher	A34614-A-PCT-USA-A (07005	9003

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EXAMINER
DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,475	FISHER ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-98 are pending in the instant application and are subject to the following restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 30-34, and 35-40, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of MDA-5 protein, classified in class 424, subclass 94.1.

II. Claims 1-3, 10-18, 30-34, and 41-49, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of mda-5 nucleic acid, classified in class 514, subclass 44.

III. Claims 1-3, 19-27, 30-34, and 50-58, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of an agent that increases the activity of an mda-5 promoter, classified in class 424, subclass 85.1.

IV. Claims 1-3, 28-34 and 60, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of an agent that acts on MDA-5 protein to

increase the functional activity of the protein, classified in class 424, subclass 94.1.

V. Claims 61-66, drawn to methods of inhibiting cell proliferation in a cell population *in vitro* by administration of MDA-5 protein, classified in class 435, subclass 4.

VI. Claims 61-66 and 77-82, drawn to methods of inhibiting cell proliferation in a cell population *in vivo* by administration of MDA-5 protein, classified in class 424, subclass 94.1.

VII. Claims 67-76, drawn to methods of inhibiting cell proliferation in a cell population *in vitro* by administration of mda-5 nucleic acid in an expressible form, classified in class 435, subclass 455.

VIII. Claims 67-76 and 83-92, drawn to methods of inhibiting cell proliferation in a cell population *in vivo* by administration of mda-5 nucleic acid in an expressible form, classified in class 514, subclass 44.

IX. Claim 93, drawn to an isolated mda-5 nucleic acid (SEQ ID NO: 4), classified in class 536, subclass 23.1.

X. Claim 94, drawn to a method of sensitizing a cell to a growth-inhibitory effect of a protein kinase C inhibitor, classified in class 435, subclass 4.

XI. Claim 95, drawn to a viral vector comprising two cancer-inhibitory genes, one of which is operably linked to a mda-5 promoter, classified in class 435, subclass 320.1.

XII. Claim 96, drawn to an isolated protein (SEQ ID NO: 7), classified in class 530, subclass 350.

XIII. Claim 97, drawn to an isolated nucleic acid (SEQ ID NO: 8), classified in class 536, subclass 23.1.

XIV. Claim 98, drawn to an isolated protein (SEQ ID NO: 9), classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mechanisms of protecting a subject against a viral infection: by administration of MDA-5 protein directly (Group I), a nucleic acid capable of expressing MDA-5 protein (Group II), an agent that increases the activity of an mda-5 promoter (Group III), and an agent that acts on MDA-5 protein to increase the functional activity of the protein (Group IV).

Claim 1 link(s) inventions of Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the

instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different methods of delivery of MDA-5 protein to inhibit cell proliferation in a population of cells *in vitro* (Group V) or in a subject (Group VI).

Claim 61 link(s) inventions of Group V and Group VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 61. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Group VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different methods of delivery of mda-5 nucleic acid to inhibit cell proliferation in a population of cells *in vitro* (Group VII) or in a subject (Group VIII).

Claim 67 link(s) inventions of Group VII and Group VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 67. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups I-IV and Groups V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different outcomes based upon the structural/functional effects of the agents administered in different subject populations: protecting a subject against contracting a viral infection or limiting a viral infection (Groups I-IV) and inhibiting cell proliferation (Groups V-VI).

Inventions of Groups I-IV and Groups VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different outcomes based upon the structural/functional effects of the agents administered in protecting a subject against contracting a viral infection or limiting a viral infection (Groups I-IV) and inhibiting cell proliferation (Groups VII-VIII).

Inventions of Groups V-VI and Groups VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mechanisms of inhibiting cell proliferation: by direct administration of an isolated MDA-5

protein (Groups V-VI) or by administration of mda-5 nucleic acid in an expressible form (Groups VII-VIII).

The nucleic acids of Groups IX and XIII, isolated proteins of Groups XII and XIV and viral vector of Group XI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups I-VIII and Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mechanisms of action: administration of MDA-5 protein (Groups I, V-VI), mada-5 nucleic acid (Group II, VII-VIII), an agent that increases the activity of an mda-5 promoter (Group III), an agent that acts on MDA-5 protein to increase the functional activity of the protein (Group IV) and any one of the above in combination with a protein kinase C inhibitor (Group X). The end result of the methods are different: protecting a subject against contracting a viral infection or limiting a viral infection (Groups I-IV), inhibiting cell proliferation (Groups V-VIII) and sensitizing a cell to a growth-inhibitory effect of a protein kinase C inhibitor (Group X). Thus, the operation, function and effects of these different methods are different and distinct from each other.

Inventions Groups I, III-VI and Groups IX, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups IX, XIII are not used in or made by the methods of Groups I, III-VI.

Inventions of Groups IX, XIII and Groups II, VII-VIII, X are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid sequences of SEQ ID NO: 4 and SEQ ID NO: 8 can be used in biologically and functionally distinct methods to prevent or limit viral infection, to inhibit cell proliferation or to sensitize a cell to a protein kinase C inhibitor.

Inventions Groups II, VII-VIII and Groups XII, XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups IX, XIII are not used in or made by the methods of Groups II, VII-VIII.

Inventions of Groups XII, XIV and Groups I, III-VI, X are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid sequences of SEQ ID NO: 7 and SEQ ID NO: 9 can be used in biologically and functionally distinct methods to prevent or limit viral infection, or to inhibit cell proliferation.

Inventions of Group XI and Groups I-VIII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group XI is not used in or made by the methods of Groups I-VIII, X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Dunston
Examiner
Art Unit 1636

jad

GERRY LEFFERS
PRIMARY EXAMINER